

REMARKS

Reconsideration of this patent application is respectfully requested. Claims 1-13, 17-20 and 28-31 are currently pending in the present application. All such claims are subject to a restriction requirement between the following Groups of claims:

1. Group I Claims: 1-11 drawn to a method for preparing a protein-polymer conjugate.
2. Group II Claims: 28-31 drawn to an insulin-PEG conjugate.

As an initial note, it appears the Examiner has not addressed claims 12-13 and 17-20. Claims 12-13 and 17 are dependent on claim 1. Claim 18 is an independent claim and claims 19-20 are dependent on it.

The Examiner argues that restriction is proper because the product and the process of using the product as described in the claims constitute patentably distinct inventions. In response, Applicant hereby provisionally elects, with traverse, the Group I claims 1-11. Applicant respectfully requests claims 12-13 and 17 be added to Group I claims. Applicant reserves the right to file a continuing application or take such other appropriate action as is necessary to preserve the non-elected inventions. Applicant does not hereby waive or abandon any rights in the non-elected inventions.

Applicant respectfully requests guidance from the Examiner as to whether claims 18-20 are included in Group I or II. As such, Applicant has not cancelled these claims and will take action upon clarification from the Examiner.

Applicant respectfully asserts that as a whole, the restriction requirement parsing out the two Groups is improper. The Examiner appears to wholly rely on the "distinct" prong of the requirement in 35 USC § 1.21 that there be "two or more independent and distinct inventions"

claimed in one application before the Director may require restriction (emphasis added). The Examiner has made no contention that the inventions of any Group are in any way "independent" of each other. While Applicant accepts the two Groups are patentably distinct from one another, they are clearly not independent inventions. The Group I claims are directed to methods of preparing a protein-polymer conjugate and the Group II claims are directed to a particular protein-polymer conjugate, specifically insulin-PEG. Thus, the two inventions are interrelated and while they may be distinct, they are clearly not independent.

Applicant also asserts that the Examiner has failed to demonstrate a *prima facie* case of undue burden, the second requirement of MPEP § 803. It is not sufficient to simply define the various claims as distinct and requiring different classifications as that is not the requirement for a *prima facie* case. The Examiner has indeed properly defined Groups I and II as two separate classes of claims, but it bears repeating that the very act of making this classification does not satisfy the *prima facie* case that is the Examiner's burden under the second prong of § 803. "The examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required." (MPEP § 808.02) This means not only classifying them separately, but also showing specifically a need for a separate field of search, and, in this case, the process for producing a protein-polymer product and a representative protein-polymer product should both fall within a single field of search.

In light of the above arguments, Applicant respectfully contends that this restriction election is improper and should be removed.

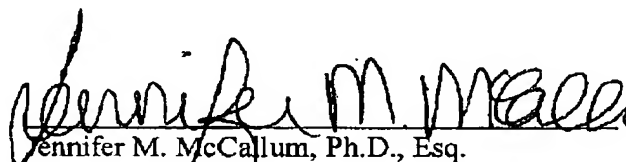
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Concluding Remarks

In view of the foregoing remarks, Applicant respectfully requests reconsideration and examination as to the merits of the application. If the Examiner notes any further matters which would be expedited by a telephonic interview, she is requested to contact Dr. Jennifer M. McCallum at the telephone number listed below.

Respectfully Submitted,

3.31.09
Date

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